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UNITED STATES DISTRICT COURT
DISTRICT OF OREGON
PORTLAND DIVISION

IMMUNOFREE, INC.,

Plaintiff,

vs.

OREGON HEALTH & SCIENCE
UNIVERSITY, dba OHSU,

Defendant.

Case No.

COMPLAINT FOR BREACH OF
CONTRACT AND DECLARATORY
JUDGEMENT PURSUANT TO
ORE. REV. STAT. 28.010-28.160

DEMAND FOR JURY TRIAL

JURISDICTION AND VENUE

1. Plaintiff Immunofree, Inc. (“Immunofree”) is a citizen of both Delaware and Connecticut, with its principal place of business in Greenwich, Connecticut.
2. Defendant Oregon Health & Science University, dba OHSU (“OHSU”), is an Oregon corporation residing in Multnomah County.
3. The Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1332(a) because there is complete diversity between the parties and the amount in controversy exceeds \$75,000.
4. The Court has personal jurisdiction because Defendant is a resident of this forum and the relevant actions leading to this dispute arose in the state of Oregon.

5. This Court is the proper venue because a substantial part of the events or omissions giving rise to the claim occurred within the District of Oregon and Multnomah County. *See* LR 3-2.

PARTIES TO THE ACTION

6. Plaintiff Immunofree is formed under the laws of Delaware with its principal place of business in Greenwich, Connecticut. Immunofree is a biomedical company with the stated mission to eliminate the need for immunosuppressive medication for transplant recipients.

7. Defendant OHSU is an academic medical facility, which provides in-patient and out-patient hospital services, training and education of health care professionals, and medical research, including the facilitation of medical clinical trials. OHSU is also vicariously liable for the negligence of its agents and employees, acting within the course and scope of their agency or employment.

GENERAL ALLEGATIONS

8. CTI Clinical Trial Services, Inc. (“CRO”), who is not a party to this action, is a contract pharmaceutical and biotechnology research organization based in Covington, Kentucky.

9. Talaris Pharmaceuticals, Inc. (“Talaris”) hired a CRO to arrange and administer a multi-center clinical trial (“Trial”), sponsored by Talaris, who is also not a party to this action.

10. The Trial was designed to be a five-year randomized controlled trial to test a new cellular therapy biologic, which was intended for recipients of kidney transplants from living donors (“Cellular Therapy”). The purpose of the Cellular Therapy was to eliminate the need for immunosuppressive drugs that kidney recipients are currently required to take after receiving a kidney to prevent rejection of the recipient’s newly transplanted kidney. Participants of the Trial who received the Cellular Therapy were required to receive a donation of stem cells from their

kidney donor simultaneously to receiving the Cellular Therapy.

11. On or about December 21, 2020, OHSU entered into an Accelerated Clinical Trial Agreement (“ACTA”) with CRO. A copy of the ACTA is attached hereto as Exhibit 1.

12. Upon information and belief, OHSU began selecting patients for the Trial on or about December 22, 2020.

13. As both a medical care provider and the administrator medical clinical trials, OHSU owes its patients the same degree of care, skill, and diligence that is ordinarily used by a physician in the same or similar circumstances as a physician in a similar community.

14. OHSU owes its patients a heightened duty of care in the screening, facilitating, and issuing of experimental medications or procedures in its medical clinical trials. OHSU owes such patients a higher duty of care than that of an ordinary physician, it owes the same duty of care as such other physicians engaged in similarly sophisticated, high-risk medical, and experimental care.

15. The screening, selection, and care of Trial patients in this case was performed by OHSU employees and/or agents in the ordinary course and scope of their agency and/or employment with OHSU.

16. Under Section 1.1 of the ACTA, OHSU was required to use reasonable efforts to select participants for the trial in accordance with the protocols set by CRO.

17. The CRO protocols required all drug recipients to meet the following criteria (among other criteria not listed herein):

- a. Recipient must be willing and able to be compliant with protocol-required visit schedule and visits required;
- b. Recipient must meet all local standard eligibility criteria for allogenic stem

cell transplants;

- c. Recipient or donor with any other medical or psychological condition that, in the opinion of the Investigator, is likely to interfere with the subject's ability to give informed consent or participate in the study;
- d. Recipients must not have any baseline condition that would require or anticipate requiring chronic or intermittent use of systemic steroids or other IS (e.g., autoimmune disease, asthma) throughout the course of the study;
- e. Recipient must not require systemic anticoagulation (e.g., for hypercoagulation disorders, deep vein thrombosis, atrial fibrillation) that cannot be temporarily interrupted which would preclude renal biopsy; and
- f. Recipient must not have contraindication to TBI according to local radiologist, e.g., previous radiation therapy at a dose which would preclude TBI, inadequate pulmonary function.

18. Under the terms of the ACTA, the sponsor of the Trial is required to indemnify OHSU from claims of adverse reaction, illness, or injury, which was directly caused by the Cellular Therapy or properly performed procedures required by the CRO protocol (hereinafter referred to as "Trial Injury").

19. If a Trial Injury occurred, the sponsor would be required to reimburse OHSU for the "reasonable and necessary costs of diagnosis and treatment" of the Trial Injury.

20. However, sponsor has no duty to indemnify OHSU or otherwise reimburse for the costs of diagnosis or treatment of any Trial Injury if the Trial Injury occurred due to OHSU's negligence or willful misconduct.

21. On or about June 28, 2023, Talaris sold the Trial and Talaris's various assets and

data related to the same to Plaintiff Immunofree.

22. Under the terms of Asset Purchase Agreement, Immunofree assumed all the rights, responsibilities, and liabilities between Talaris and OHSU for the Trial under the ACTA, including serving as the new sponsor for the Trial.

23. On or about July 30, 2021, OHSU enrolled one patient, referred herein as “Patient,” in the Trial.

24. Upon information and belief, Patient had various comorbidities and preexisting conditions, including, but not limited to: obesity, diabetes mellitus, coronary artery disease, myocardial infarction, coronary artery bypass surgery, hypothyroidism, hypertension, and hyperlipidemia. The combination of these pre-existing conditions should have precluded the Patient’s participation in the Trial under the CRO protocols.

25. Stem cell transplant providers typically set age limits for recipients and donors, and prevent recipients with major health problems from receiving stem cell transplants. Upon information and belief, OHSU failed to adhere to its own protocols by enrolling Patient into the Trial.

26. Upon information and belief, Patient lives approximately four hours away from OHSU where the Trial was administered.

27. Upon information and belief, OHSU knew or should have known when enrolling Patient in the Trial that Patient’s home was far away from OHSU such that Patient faced hardship with the protocol-required visit schedule, which should have precluded her from participating in the Trial under CRO protocols.

28. Upon information and belief, OHSU knew or should have known when enrolling Patient in the Trial that given the Patient’s comorbidities and preexisting conditions, Patient

would be at an unaccountably high risk of an adverse event, which should have precluded her participation in the Trial under the CRO protocols.

29. At some point after her participation in the Trial and receiving the Cellular Therapy, Patient developed Chronic Graft Versus Host Disease (“GVHD”).

30. Chronic GVHD is a condition that can occur when donor bone marrow or stem cells attack the recipient’s cells.

31. Upon information and belief, were it not for OHSU negligently enrolling Patient in the trial, she would not have developed Chronic GVHD.

32. On or about February 24, 2022, OHSU began administering treatment to Patient for GVHD, which requires daily treatment with drugs including Jakafi and monthly Immunoglobulin infusions. OHSU requires that the monthly infusions occur at OHSU in Portland, Oregon. As a result, the monthly infusions require Patient to travel approximately eight hours round trip from her home to OHSU to receive the treatment.

33. Pursuant to the terms of the ACTA, these treatments have been paid by the sponsor to OHSU directly, and not billed through any sort of insurance.

34. Monthly treatment with Jafaki costs approximately \$16,686.00.

35. Monthly Immunoglobulin treatments and associated costs total approximately \$26,105.00.

36. To date, Patient’s treatment cost exceeds \$1,400,000.00.

37. At no point has OHSU provided Patient with the opportunity to seek care outside of OHSU’s facilities, despite the significant cost and travel time associated with OHSU’s services.

38. OHSU refuses to bill Patient’s insurance for Patient’s care and instead continues

to bill CRO. For example, on or about December 14, 2023, CRO forwarded Immunofree an outstanding invoice for Patient's treatment from OHSU, totaling \$109,495.81. On January 23, 2024, CRO received another invoice for \$409.38.

39. Upon information and belief, OHSU intends to continue to invoice CRO with the expectation that Immunofree reimburse it for all of Patient's care-related costs.

40. Immunofree's priority has always been Patient's care. Immunofree has repeatedly alerted OHSU to its concern that Patient is being denied access to medical care of Patient's choosing due OHSU's refusal to bill Patient's insurance and allow Patient access to care outside of OHSU's campus.

41. In short, OHSU negligently enrolled Patient in the Trial and then held Patient captive in its system by refusing to allow Patient to seek medical care outside of its campus.

42. Out of concern for the Patient, Immunofree worked collaboratively with Patient to provide Patient with resources, support, and access to insurance to ensure Patient has convenient, quality access to care. As a result, Immunofree incurred \$1,000,000.00 in damages to ensure Patient has access to care for injuries sustained due to OHSU's negligent Trial enrollment.

FIRST CAUSE OF ACTION

Breach of Contract

43. Plaintiff realleges paragraphs 1 through 42 and incorporates the same as though fully set forth herein.

44. OHSU entered into the ACTA, which constitutes a valid and binding contract between OHSU and the sponsor of the Trial.

45. Through the Asset Purchase Agreement, Immunofree assumed all the rights, responsibilities, and liabilities of Talaris as sponsor for the Trial under the ACTA.

46. Under the ACTA, OHSU was required to use reasonable efforts to select participants for the Trial in accordance with the CRO protocols.

47. Upon information and belief, OHSU violated the CRO protocols in breach of the ACTA by negligently selecting Patient for the Trial when OHSU knew or should have known that Patient was not fit for the Trial under the CRO protocols.

48. OHSU further violated the ACTA by requiring Talaris and Immunofree as sponsors of the Trial to pay for Patient's treatments because due to patient's health and comorbidities, Patient should have never been enrolled in the Trial in the first place.

49. As a direct and proximate result of OHSU's breach, OHSU is seeking payment for Patient's treatment from Immunofree (via CRO).

50. As a direct and proximate result of OHSU's breach, Talaris suffered damages in the total amount of approximately \$1,354,383.94 that it improperly paid towards Patient's care.

51. As the successor of Talaris, Immunofree is entitled to recover the damages incurred by Talaris as a result of OHSU's breach.

52. As a direct and proximate result of OHSU's breach, Immunofree incurred an additional \$1,000,000.00 in damages to ensure Patient has access to care for injuries sustained due to OHSU's negligently Trial enrollment.

SECOND CLAIM FOR RELIEF

Breach of Contract

(Failure to Indemnify Immunofree)

53. Plaintiff incorporates and realleges paragraphs 1 through 42 as set forth here in full.

54. OHSU entered into the ACTA, which constitutes a valid and binding contract

between OHSU and the sponsor of the Trial.

55. Through the Asset Purchase Agreement, Immunofree assumed all the rights, responsibilities, and liabilities of Talaris as sponsor for the Trial under the ACTA.

56. Under the ACTA, OHSU was required to use reasonable efforts to select participants for the Trial in accordance with the CRO protocols.

57. Under the ACTA, OHSU was required to indemnify and hold harmless the sponsor of the Trial for any third-party claims “directly attributable to [OHSU’s] negligence in its conduct of the Study.”

58. Upon information and belief, OHSU materially violated the protocols in breach of the ACTA by negligently selecting Patient for the Trial when OHSU knew or should have known that Patient was not fit for the Trial under the CRO protocols.

59. OHSU further violated the ACTA by failing to indemnify and hold harmless Talaris and Immunofree for Patient’s claims and the costs of Patient’s required treatments because OHSU negligently enrolled Patient in the Trial.

60. As a direct and proximate result of OHSU breach, Talaris suffered damages in the total amount of at least \$1,354,383.94.

61. As the successor of Talaris, Immunofree is entitled to recover the damages incurred by Talaris as a result of OHSU’s breach.

62. As a direct and proximate result of OHSU’s breach, Immunofree will continue to suffer future damages.

63. As a direct and proximate result of OHSU’s breach, Immunofree incurred an additional \$1,000,000.00 in damages to ensure Patient has access to care for injuries sustained due to OHSU’s negligent Trial enrollment.

THIRD CLAIM FOR RELIEF

Oregon Uniform Declaratory Judgment Act

(Two Counts)

64. On or about January 4, 2024, Immunofree informed OHSU that Immunofree reasonably believed that the sponsor of the Trial (either Talaris or Immunofree) should not have been held responsible for Patient’s treatment costs because Patient was negligently selected for participation in the Trial by because Patient did not meet the criteria set forth in the CRO protocols.

65. OHSU refused to provide its local protocols and trial criteria to Immunofree and claimed that Immunofree would continue to owe OHSU for Patient's ongoing treatment, which OHSU wrongfully attributes to the Cellular Therapy and not OHSU’s own negligence in enrolling Patient in the Trial.

66. Immunofree responded that, although it reasonably believed it should not be held responsible for Patient’s treatment, OHSU was further violating the ACTA by failing to provide “reasonable” treatment to Patient, by requiring Patient to travel between her home in Bend, Oregon, and OHSU’s Portland campus—approximately eight hours round trip for each treatment.

67. Immunofree and OHSU have failed to resolve their disputes concerning whether Immunofree and/or Talaris should have been responsible for Patient’s past treatment and whether Immunofree should continue to be responsible for Patient’s future treatment under the ACTA.

68. Pursuant to Ore. Rev. Stat. § 28.120, the purpose of Oregon’s Uniform Declaratory Judgments Act “is to settle and to afford relief from uncertainty and insecurity with respect to rights, status, and other legal relations, and is to be liberally construed and administered.”

69. There is a justiciable controversy under the Oregon Uniform Declaratory

Judgments Act because there is an existing set of facts that threaten Immunofree's legal rights, and the controversy can be resolved with respect to Defendant's alleged ongoing damages.

70. This controversy is ripe for adjudication given Patient's ongoing treatment costs and the parties' inability to resolve this matter.

Count 1 – Declaration that Immunofree is not Liable for Patient's Treatment

71. Plaintiff incorporates and realleges the foregoing paragraphs as set forth here in full.

72. Upon information and belief, OHSU negligently admitted Patient into the Trial even though OHSU knew or should have known that she did not meet all the CRO protocols and therefore did not qualify for the Trial.

73. Under the terms of the ACTA, the Trial sponsor is not liable for any injury or illness caused or exacerbated by the Trial if such injury or illness was caused by the negligence of OHSU.

74. Because Patient's Chronic GVHD diagnosis was as a result of her negligent admission into the Trial by OHSU, Talaris was not liable to pay for any of the Patient's care costs reimbursed to OHSU and Immunofree was not liable for Patient's prior treatment and is not liable for her ongoing treatment.

75. Immunofree seeks a declaration that it is not, nor has it or its predecessors ever been, liable for Patient's treatment of Chronic GVHD or associated Trial costs.

Count 2 – Declaration that Patient's Treatment Is Not Reasonable

76. Plaintiff incorporates and realleges the foregoing paragraphs as set forth here in full.

77. Although Immunofree maintains that it is not, nor has it or its predecessors ever

been, liable for Patient's treatment of Chronic GVHD, Immunofree's alleged responsibility to pay for Patient's Trial Injury limited to "reasonable treatment."

78. Upon information and belief, OHSU has been providing Patient with the treatment for Patient's Chronic GVHD at OHSU's Portland campus.

79. Upon information and belief, Patient lives in Bend, Oregon, meaning she must travel approximately eight hours round trip to receive her treatments from OHSU.

80. The time and distance required for Patient to travel imparts unnecessary and extensive costs on the Patient and Immunofree.

81. Accordingly, Immunofree seeks a declaration that Immunofree is not responsible for any of Patient's treatment costs because OHSU's treatment of Patient's Chronic GVHD is not "reasonable" under the terms of the ACTA.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

- A. Monetary damages in the amount of \$2,354,383.94, for payments made by Immunofree or its predecessors for Patient's treatment, which is required as a result of OHSU negligently admitting Patient into the Trial, plus interest;
- B. Declaring that neither Immunofree, nor its predecessors, were or are liable for Patient's treatment, which is required as a result of OHSU negligently admitting Patient into the Trial;
- C. Declaring that neither Immunofree, nor its predecessors, were or are liable for Patient's treatment, to the extent the treatment is unreasonable under the terms of the ACTA;
- D. An award of fees and costs; and

E. Such other and further relief as the Court deems necessary or just.

JURY DEMAND

Plaintiff demands a jury trial on all issues so triable.

DATED this 21st day of August, 2024.

SNELL & WILMER L.L.P.

s/ Lea K. Schneider

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